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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,937	11/16/2005	Jacques Latrille	065691-0385	9440

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,937	LATRILLE ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 11 is pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/2007 has been entered.

Claims 1-10 are canceled, claim 11 is newly added, and claim 11 has been considered on the merits.

Claim Objections

Claim 11 is objected to because of the following informalities: the intended use of "increasing recalcification" appears to be "increasing recalcification time" rather than the reaction itself. Appropriate correction is required.

The term "immunostimulation" is not disclosed in the specification. Instead, immunomodulation is disclosed. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bini (US 6,020,181) in view of Nikonov et al. (1999) in further view of Basanova et al. (2002).

Claim is drawn to a method for inducing fibrinolysis or thrombolysis, for increasing recalicification or immunostimulation, or for reducing blood pressure in a stent implantation area of a blood vessel by angioplasty, comprising implanting to a subject a stent covered with a cladding, which consisting a liposome destabilase complex obtained from medicinal leeches using an affinity chromatographic column having 6-keto-prostaglandin antibodies, eluting the purified liposome destabilase complex with a high ionic strength solution,

Bini teaches an implantable stent coated with an enzyme inhibiting thrombus formation and an example of such enzyme being obtained fibrinolytic enzymes from leeches with a reference of Zavalova et al., which discloses a destabilase (see column 3, lines 15-16; column 6, lines 46-49). The limitation of "cladding" is considered as any layer such as a coating. Bini teaches that a fibrinolytic enzyme can be employed as a coating (see column 10, line 16).

Nikonov et al. teach the liposome destabilase complex isolated from leeches by affinity chromatography using 6-keto-prostaglandin antibodies (see Material and Methods) and having a fibrinolytic activity. Nikonov et al. also teach the elution of liposome destabilase complex with 0.2 M glycine, which is a high ionic solution well known in the art. Since the liposome destabilase complex of Nikonov et al. is identical

as the liposome destabiliase complex of the current application, the property of the complex having anticoagulating and immunomodulatory activity would be also the same.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the liposome destabilase complex of Nikonov et al. for the stent taught by Bini.

The skilled artisan would have been motivated to make such a modification because Bini teaches a stent coated with a fibrinolytic enzyme and that such enzyme is present in the destabilase complex of Nikonov et al. Furthermore, Bini discloses the fibrinolytic enzyme preferably in combination with a thrombolytic agents to improve thrombolytic and fibrinolytic therapy (see Abstract). Since the destabilase complex of Nikonov et al. has both fibrinolytic activity and anti-thrombin (thrombolytic) activity provided by hirudin in the complex, a person of ordinary skill in the art would have been motivated to use the complex of Nikonov et al. in the stent support of Bini.

The person of ordinary skill in the art would have had a reasonable expectation of success in the use of the complex of Nikonov et al. as a coating of a stent taught by Bini because the stent of Bini can successfully have a coating of enzymes having a thrombolytic and a fibrinolytic activity.

In regards to the limitation of "so as to obtain a release of a substance ... immunomodulating properties", this limitation is a mere result of the method step and therefore does not limit the steps of method claimed in the current invention. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993);

Griffin v. Bertina, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

With regard to the intended use for increasing immunostimulation, the stent of Bini in view of Nikonov et al. would have immunomodulating property from destabilase complex, and therefore, a person of ordinary skill in the art would recognize that immunomodulating property would be considered either immunosuppressing or immunostimulating. Since it is well known in the art that medicinal leech can immunostimulate, the intended use of the instant invention would be carried out by the intrinsic property of destabilase purified from medicinal leech.

Although Bini in view of Nikonov et al. do not particularly teach the intended use of increasing recalcification time or reducing blood pressure in a stent implantation area of a blood vessel treated by angioplasty, since the stent with liposome destabilase complex coated as taught by Bini in view of Nikonov et al. is substantially similar, if not identical, as the stent claimed in the instant invention, the stent of Bini in view of Nikonov et al. is capable for the intended uses disclosed in the current application.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "reducing blood pressure in a stent implantation area of a blood vessel treated by angioplasty" does not affect the patentability of the claimed method. Methods are

defined by their constituent steps, not by an intended use or application. Since the intended use limitations are based on the functional properties of destabilase complex present in the stent, and the destabilase complex of Bini in view of Nikonov et al. is identical as that of the current invention, the implantation of such stent would have the same effect as the intended use claimed in the current invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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